LIBRARY SUPPLEME COURT U.S.

la 568

JAN 18 1950

ON THE SELECTION OF THE

Optomer Tent., 1949

CREAL R. EWING. PRINCIAL SECURITY APRILLED APRILLED IN AL. APPELLANDS.

Mysericen & Carrieren

Infanticide (homicide of infants under	1		. 0	1	1	
1 year of age)	3(174)	3(154)	3(149)	370 33	300 33	340.00
Honicide by firears	4,922	4,966		3(0.1)	3(0.1)	3(0.1)
Somicide by cutting or plercing in-	3,562	4,900	4,029	5.4	8.5	5.1
struments	1,981	2,159	1,887		1.5	1.4
Honicide by other means	1,652	1,659	1,546	1.2	1.2	1.2
	2,000	1,000	1,540	1.6	1.2	. 1.4
Accidental deaths	99,579	98,038	95,918	69.4	70.1	72.7
Railway accidents (except collisions with			4.			
motor vehicles)	2,663	2,937	3,520	1.9	2.1	2.5
Motor-vehicle accidents	52,697	33,411	28,076	22.8	25.9	21.8
(a) Collisions between automobiles and						
trains	1,736	1,705	1,705	1.2	1.2	1.8
(b) Collisions Setween automobiles and		**				
streetcars	108	174	163	0.1	0.1	0.1
(c) Automobile accidents (except						1
collisions with trains or street-						
(era)-	30,074	30,827	25,672	21.0	22.0	19.4
(d) Motorcycle accidents (except		,			. '	
callisions with sutamobiles)	785	707	538	0.5	0.5	0.4
Streetcar and other road-transport			. 0.			
accidenta	597	754	836	0.4	0.5	0.8
						1
(a) Streetcar accidents (except				1		. ,
collisions with trains or motor	1					
vehicles)	422	544	618	0.3	. 0.4	0.5
(b) Other and unspecified road-transport	-			1		
accidente-	175	190	218	0.1	0.1	0.2
Mater-transport accidents-	1,244	1,056	1,021	0.9	0.8	0.8
Accidents in mines and quarries	2,013	1,851	5,552	1.4	1.5	2.7
Agricultural and forestry accidents	1,509 2,287	1,275	1,352	1.1	0.9	1.0
(a) Accidents involving agricultural	2,401	2, 455	2,416	1.6	1.8	1.8
machinery and vehicles	914	970	1,006	0.0	0.7	A 0
(b) Injury by annimals, in agriculture—	278	297	326	0.6	0.7	0.8
(c) Other agricultural accidents	666	780	809	0.5	0.6	0.2
(d) Accidents involving forestry	1		609	0.5	0.6	0.6
machinery and vehicles	62	69	40	0.0	0.0	0.0
(e) Other forestry accidents	367	337	235	0.5	0.2	0.0
Other accidents involving machinery	1,208	1,175	1,225	0.8	0.8	0.9
Food poisoning	318	369	459	0.2	0.5	0.3
Accidental absorption of poisonous gas-	1,958	1,874	2,151	1.4	1.5	1.6
(A) Utility gas	1,009	1,045	1,273	0.7	0.7	1.0
(B) Motor-vehicle exhaust gas-	285	256	205	0.2	0.2	. 0.2
(C) Other carbon monoxide gas-	354	354	595	0.2	0.5	0.3
(I) Other poisonous gases	290	241	260	. 0.2	0.2	0.2
Acute accidental poisoning by solids or	1					
liquids-	1,504	1,586	1,552	1.0	1.1	1.2
(A) Arsenic and compounds	48	68	58	0.0	0.0	0.0
(B) Barbituric acid and derivatives	418	436	592	0.3	0.5	0.3

³ Included in figures for homicide.

	the same waterway	210	1. 405	1 100	. 0.1	1 0.1	0.1
	(X) Other and unspecified substances	670	.670	658	0.5	0.5	0.5
180	Conflagration	3,515	3,017	p2, 914	2.3	2.2	2.2
181	Accidental burns (except conflagration)	4,685	4,856	5,105	3.3	3.5	3.9
182	Accidental mechanical suffocation	1,930	1,605	1,483	1.3	1.1	1.1
183	Accidental drowning-	5,737	5,577	5,676	4.0	4.0	4.3
184	Accidental injury by firearms	2,386	2,816	2,454	1.7		1.9
185	Accidental injury by cutting or piercing			-,	***	2.0	1.5
	instruments	285	317	329	.0.2	0.2	0.2
186	Accidental injury by fall or crushing	24,397	23,028	23,818	17.0	16.5	18.0
	(a) Pall	23,961	22,581	23,333	16.7	16.1	
	(b) Crushing-	436	447	485	0.3		17.7
187	Cataclysm (all deaths attributed to a	157,			0.3.	0.3	0.4
	cataclysm, regardless of their nature)	393	148	300	0.3	0.1	0.2
183	Injury by animals (not specified as	1				0.1	. 0.2
	venomous or occurring in the course of						
	agricultural and forestry operations)	113	142	152	0.1	0.1	0.1
189	Hunger or thirst	26	27	29	0.0	0.0	0.0
190	Excessive cold	270	193	277	0.2	0.1	0.2
191	Excessive heat	540	182	255	0.4	0.1	
192	Lightning-	538	231	268	0.2	0.2	0.2
193	Accidents due to electric currents (ex-					0.2	0.2
	cept lightning)	867	725	620	0.6	0.5	0.5
194	Poisoning by venomous animals (not		20		0.0	0.5	0.5
,	occurring in the course of agricultural						
	and forestry opera ions)	64	62	50	0.0	0.0	
195	and forestry operations)————————————————————————————————————	6,255	6,441	6,258			0.0
	(a) Sequelae of preventive immunization,	. 0,,200	0,441	0,230	4,4	4.6	4.7
	inoculation, or vaccination	16	. 19	14	0.0	0.0	
, , , ,	(b) Other accidents due to medical or		3 13	14	0.0	0.0	0.0
	surgical intervention-	44	47	, 50	0.0	0.0	
	(c) Lack of care of the newborn	29	46	22	0.0	1	0.0
	(d) Obstruction, suffocation, or		40		0.0	0.0	0.0
	puncture by ingested objects-	1,203	1,076	897	0.8	0.0	
	(e) Other and unspecified accidents-	4,960	5,253		3.5	0.8	0.7
	A. S.	4, 100	3,233	5,275	3.5	5.9	4.0
196	Deaths of military personnel during						
	operations of war-		. 20	126		0.0	
. 197	Deaths o civilians due to operations of		. 20	176	Ņ	0.0.	0.1
*	war		1	9	0	0.0	
198	Legal executions	153	129		-	0.0	0.0
		133	. 129	135	0.1	0.1	0.1
	XVIII Ill-defined and unknown		1				
	causes	17,850	12 520	10.100	20.4		
		17,050	. 17,580	18,166	12.4	12.6	13.3
109	Sudden death-	1,149	1 055	1 152	0.0	200	
200	Ill-defined and unknown causes		1,055	1,352	0.8	0.8	1.0
	(a) Ill-defined-	16,701	16,525	16,814	11.6	11.8	12.7
	(b) Found dead (cause unknown)	694	6,931	6,909	5.2	. 5.0	5.2
	(c) Unknown or unspecified cause	1	695	777	0.5	0.5	0.6
		8,496	8,901	9,128	5.9	6.4	6.9

In the United States District Court

FOR THE DISTRICT OF COLUMBIA

Civil Action No. 5298-48

MYTINGER & CASSELBERRY, A CALIFORNIA CORPORA-

OSCAR R. EWING, FEDERAL SECURITY ADMINISTRATOR; J. HOWARD MCGRATH, ATTORNEY GENERAL; PAUL B. DUNBAR, COMMISSIONER OF FOOD AND DRUGS; CHARLES W. CRAWFORD, ASSOCIATE COMMISSIONER OF FOOD AND DRUGS; GEORGE P. LARRICK, ASSISTANT COMMISSIONER OF FOOD AND DRUGS; AND LOUIS D. ELLIOTT, ASSISTANT COMMISSIONER OF FOOD AND DRUGS; DEFENDANTS

STATEMENT AS TO JURISDICTION

The defendants-appellants, having this day presented their petition for appeal, now pursuant to United States Supreme Court Rule 12, paragraph 1, file this their statement of the basis upon which it is contended that the Supreme Court of the United States has jurisdiction on a direct appeal to review the final decree of permanent injunction in question, and should exercise such jurisdiction in this case.

OPINION BELOW

The district court delivered no written opinion or discussion of the case, but did make certain findings of fact and conclusions of law in connection with the entry of the decree in question. Copies

of these findings and conclusions, and of the final decree herein, are attached to this jurisdictional statement.

JURISDICTION

The appeal herein is from a final decree made and entered by a United States District Court for the District of Columbia specially constituted under 28 U.S. C. 2282 and 2284 upon the plaintiff's application for an interlocutory and permanent injunction to restrain the enforcement, operation, or execution of an Act of Congress, to wit, a part of Section 304(a) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1044, 21 U.S. C. 334(a), for repugnance to the due process clause of the Fifth Amendment to the Constitution of the United States.

The Supreme Court of the United States has jurisdiction to review by direct appeal the judgment and decree complained of by the provisions of 28 U. S. C. 1253 and 2101(a). The following decisions are believed to sustain the jurisdiction of the Supreme Court to review the judgment on direct appeal in this case. Jameson & Co. v. Morgenthau, 307 U. S. 171; Phillips v. United States, 312 U. S. 246; and California Water Service v. Redding, 304 U. S. 252.

6

The final decree appealed from was made and entered on December 14, 1949.

The application for appeal was presented on January 9, 1950.

QUESTIONS PRESENTED

Section 304(a) of the Federal Food, Drug and Cosmetic Act permits more than one libel against different articles similarly misbranded "when the Administrator has probable cause to believe from facts found, without hearing, * * * that the

misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer." The principal questions presented are:

- (1) Whether the above provision is unconstitutional because the Administrator may act without holding a hearing prior to authorizing the judicial proceeding.
- (2) Whether the District Court lacked jurisdiction to review the Administrator's determination of probable cause, or to determine, in advance of the libel proceedings, whether the appellee's labeling is misleading.
- (3) If these questions are not both answered in favor of the appellants, the additional questions raised in the assignment of errors will also be presented. These include (a) whether the District Court erred in holding that the action of the administrative officials was without reasonable basis, and (b) whether the District Court seriously erred in excluding evidence offered by the Government and improperly admitting evidence, sometimes of the same type, offered by the plaintiff.

STATUTE INVOLVED

The statute of the United States that is involved is the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. 301 et seq. The particular section of that Act involved is Section 304(a), 52 Stat. 1044, 21 U. S. C. 334(a), which provides in pertinent part as follows:

(a) Any article of . . . drug . . . that is . . . misbranded when introduced into or while in interstate commerce . . . shall be

liable to be proceeded against . . . on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided however, That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding. and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel forcondemnation proceedings under this Act, or (2) when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. * (Italics ours.)

The District Court held that the italicized portion of the statute is unconstitutional under the due process clause of the Fifth Amendment to the Constitution.

STATEMENT

Mytinger & Casselberry, Inc., is the exclusive national distributor of "Nutrilite Food Supplement", an encapsulated concentrate of alfalfa, watercress, and parsley fortified with synthetic vitamins and sold in a combination package with mineral tablets. The labeling consists in part of various editions of a booklet entitled "How to Get Well and Stay Well", a carefully conceived writ-

ing that is used by salesmen in soliciting contracts calling for delivery of a year's supply of Nutrilite, which costs approximately \$200 per year payable in monthly installments.

An edition of the bookles in use until May 1948 was the basis for an indictment returned in the Southern District of California against Mytinger & Casselberry, a partnership, and Lee S. Mytinger and William S. Casselberry, charging a deliberate offense against the Federal Food, Drug, and Cosmetic Act. The booklet was revised during the investigation which preceded the indictment, and the 58 page booklet, involved in the present case, was the result.

On September 28, 1948, the defendant Charles W. Crawford, Associate Commissioner of Food and Drugs, recommended that a seizure case be instituted against a shipment of "Nutrilite Food Supplement" found in Belleville, New Jersey. The action was filed on October 6, 1948, upon a libel that alleged that the drug was misbranded when introduced into interstate commerce because of false labeling representations as to its therapeutic effect. The statements on which the charge of misbranding was based were taken from pages 37-58 of the booklet.

On September 30, another seizure recommendation came before Mr. Crawford in the regular course of business based upon the same alleged misbranding. With the papers was a finding of fact in writing signed by Robert C. Butz, a medical officer of the Food and Drug Administration, dated September 30, 1948 which stated that "Nutrilite Food Supplement" when taken as directed would not be effective in the treatment of a number of symptoms and conditions that were enumerated. Mr. Crawford, after considering the finding which advised him of the medical facts, and after considering the 58-page booklet (more particularly pages 37-58) which was a part of the labeling, concluded that there was probable cause to believe and that he did believe that the labeling of the drug would be in a material respect misleading to the injury or damage of the purchaser or consumer. His action was taken in accordance with 21 U. S. C. 334(a), and thereafter 3 additional libel suits were recommended on behalf of the Federal Security Agency and were filed by the appropriate United States Attorneys.

Subsequent revisions of the booklet came before defendants Larrick and Dunbar, and similar determinations of probable cause were made on December 2 and 9. Libel suits were filed on the basis of these determinations.

This suit was filed on December 30, 1948. On January 24, 1949, Judge David A. Pine of the United States District Court for the District of Columbia, questioned the authority of Defendants Crawford, Larrick, and Dunbar, as delegatees, to make the probable cause determinations. The defendants were given an opportunity to present the matter to the Federal Security Administrator, and on January 28, 1949, Acting Administrator J. Donald Kingsley made the same determinations. The motion to dismiss was renewed, and Judge Pine granted it on March 3, 1948.

An amended complaint was filed the same day. It alleged that the multiple seizure provisions of 21 U. S. C. 334(a) were unconstitutional under the due process clause of the Fifth Amendment in failing to provide for a hearing prior to the determination of probable cause (Par. 18(c)). Arbi-

trary and capricious action on the part of the defendants in the administration of the Federal Food, Drug, and Cosmetic Act also was alleged (Part 9, 11, 12, 15, 18(d), 13, 14, 16, 18, 19, 20, 21, 22 and 26).

Application was made for a three-judge statutory court. District Judge Edward A. Tamm granted a temporary restraining order on March 4. 1949. After a hearing on defendants' motion to dismiss, the three-judge court granted a temporary injunction on April 6, 1949, without hearing evidence and without making findings of fact.

Defendants answered, challenging the Court's jurisdiction to try the issue whether plaintiff's labeling was materially misleading and alleging that they had acted pursuant to 21 U.S. C. 334(a).

A petition for writs of prohibition and/or mandamus was filed in the Supreme Court on the ground that the district court was acting in excess of its jurisdiction in undertaking a trial de novo on the issue whether the plaintiff's labeling was materially misleading. The petition was denied on May 16, 1949. No. 597 Misc., October Term, 1948. 337 U. S. 902.

The case was tried in October, 1949, on two issues: (1) the constitutionality of the provision of Section 304(a) of the Federal Food, Drug, and Cosmetic Act under which the defendants made their administrative determinations, and (2) whether the defendants acted arbitrarily, unlawfully, oppressively and capriciously in making the determinations without affording the plaintiff a preliminary administrative hearing.

The Court found that Nutrilite is not harmful per se (Finding 5), that the administrative determinations of probable cause were made ex parte (Findings 17, 23, 29, 30 and 35), that no separate issues of fact or law, and no public emergency,

necessitated more than one libel suit (Findings 22, 42), and that damage, through loss of potential sales and costs of litigation, followed the filing of the suits. The Court concluded that the portion of section 304(a) of the Federal Food, Drug, and Cosmetic Act, referred to above, was unconstitutional and that defendants should be permanently enjoined from enforcing it against plaintiff (Concl. 1).

THE QUESTIONS ARE SUBSTANTIAL

A. The Constitutional Question

The District Court has held unconstitutional that part of Section 304(a) which permits the Administrator to recommend the institution of multiple seizure suits, i.e., civil actions for condemnation against more than one shipment of a drug, each shipment alleged to be misbranded in the same way, when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the labeling of the misbranded drug would be in a material respect misleading to the injury of the purchaser or consumer. The provision was held to be repugnant to the due process clause of the Fifth Amendment because of its failure to provide the

Other findings were made as to the arbitrary and capricious action of the defendants (Findings 9, 12(e) and (f), 13-18, 21-22, 24, 26, 29-32, 35, 38-43) and the good faith of the plaintiff (Findings 8-10, 12-13, 19-20). No conclusion of law followed these findings, but the Court did conclude that the defendants acted arbitrarily, oppressively, and capriciously in instituting multiple libel proceedings without first affording the plaintiff a hearing on the issue whether there was probable cause to believe that the labeling was misleading in a material respect (Concl. 4). Since these findings and the conclusions do not bear upon the Supreme Court's jurisdiction to review this case on direct appeal they will not be discussed further here. Jameson & Co. v. Morgenthau, 307 U.S. 171.

shipper an opportunity for a preliminary hearing before the Administrator prior to the administrative "probable cause" decision.

The express language of Section 304(a) clearly excludes a preliminary administrative hearing, and . we respectfully submit that the section does not contravene the due process clause of the Fifth Amendment. If the provision of the statute which imposes conditions upon the bringing of more than one action based upon the same alleged misbranding, were not in the law, a shipper of an article made. offensive and illicit because of misbranding who forwarded his drug into many parts of the United States would have no right to complain that his product was being proceeded against in each jurisdiction where found. A person who has violated the same law in different transactions in 16 jurisdictions, and has been prosecuted in each jurisdiction for his transgression, has no constitutional right to insist that no more than one prosecution be brought. And a claimant of seized merchandise would have no immunity from all but one seizure. The restrictions upon multiple actions found in Section 304(a) were not devised to take from the citizen any rights he had had. Rather, Congress imposed a limitation upon administrative action to stay the hand of enforcement in specific cases.

The determination of probable cause, authorized by Section 304(a), is preliminary in nature as a predicate to the institution of multiple law suits. After institution the claimant may defend each action or may consolidate them for a single defense. 21 U. S. C. 334(b). In such defense, he is entitled to a complete trial on the merits of the Government's claimed right to condemnation. But Congress provided that no hearing be held in connec-

tion with the probable cause determination in order to make possible the prompt application of the Act against fraudulent articles, dangerous articles, and seriously misleading articles. The provision inquestion was an attempt to strike a balance of interests in protection of both the consuming public and shippers of commodities.

While the Constitution may require a hearing by an administrative agency when amissue is committed to administrative adjudication rather than to judicial determination, it obviously does not require an administrative hearing as a prerequisite to an administrative agency's right to report facts to prosecuting officials for trial and determination in a district court. The Constitution does not require that those functions of Government that traditionally have been conducted as investigative and reporting activities preliminary to a law suit must be conducted by judicial methods.

In considering the due process contention it is appropriate to inquire as to the nature of the "property" that is being taken as a result of the administrative determination of probable cause. Cf. Federal Communications Commission v. W. J. R., The Goodwill Station, 337 U. S. 265. The determination does not have the effect of finally adjudicating the character of the drug. The drug can be condemned only after a complete trial at which the claimant may present witnesses and arguments to show that the article is not misbranded.

The District Court apparently has held that whenever the property of a person is temporarily taken into custody of law pursuant to judicial process, a denial of due process results unless such

individual has had an opportunity to be heard before administrative officials prior to such deprivation. It is clear that this theory, if applicable in . a case of property, should likewise be applicable with even greater force in a case where the liberty of an individual is at stake. But an indictment returned by a grand jury, which does not grant the defendant a hearing, or indeed any notice of its proceedings, and the subsequent commitment of the accused pending trial are not violative of the due process clause. The Supreme Court has held that an indictment; fair on its face, returned by a regularly constituted grand jury conclusively determines the existence of probable cause for the purpose of holding the accused to answer. Ex parte United States, 287 U.S. 241.

Thoranalogy to the case at bar is clear. The accused in a criminal proceeding has the opportunity to vindicate himself at trial. So, too, here the drug may be vindicated at trial, but due process does not require that a prospective claimant be given notice and opportunity to be heard by the Administrator before the Administrator determines that probable cause exists and recommends multiple seizures.

B. The District Court Was Without Jurisdiction , to Review the Probable Cause Determinations or to Try the Issue Whether Plaintiff's Labeling Was Misleading

By Section 304(a), Congress has established a procedure for the protection of the consumer against misleading as well as dangerous labeling through multiple libel actions which may be instituted upon an administrative determination of

probable cause. The claimant is protected against harassment by his right to consolidate the cases for a single trial in any of the districts he may select. Section 304(b), 21 U.S. C. 334(b). The history of the statute set forth below shows 2 that

² Under the Federal Food and Drugs Act of 1906, 34 Stat. 771, goods that were adulterated or misbranded were subject to seizure wherever found, and multiple seizures regularly were made. The Act of 1906 was revised comprehensively in 1938. Bills originally proposed provided for executive seizures of articles "dangerous to health" (S. 2000, Sec. 16(a), and S. 2800, Sec. 16(a), 73rd Cong., 2d Sess. Dunn, Federal Food, Drug, and Cosmetic Act (1938) 61, 81, 102) and placed no limita-tion on the number of libel actions. This was subsequently redrafted to allow the United States district courts to restrain a multiplicity of seizures in specified cases. See S. 2800, Section 19(c), Dunn, p. 105. The Senate at one time, accepted an amendment prohibiting multiple seizures except after a judicial show-cause order proceeding. S. Rep. 361, 74th Cong., 1st Sess., Part 2, p. 11, Dunn, pp. 263, 389, 399, 468-469. later draft eliminated the provision for executive seizures, and authorized multiple libel actions in case of misbranding when the Secretary had probable cause to believe from facts found by him that the article was so misbranded as to render it imminently danger as to health or when the alleged misbranding had been the subject of a prior judgment. Dunn, pp. 505-506.

Three further changes were made, all pertinent here. A provision was added authorizing multiple seizure in éases where the Secretary had probable cause to believe that the misbranding was in a material respect false, misleading or fraudulent. *Dunn*, pp. 546, 558. The House Committee Report (H. Rept. 2755; 74th Cong., 2d Sess., *Dunn*, pp. 550.

558) stated:

"There are two substantive changes made by this committee." One is that multiple seizures would be permitted in cases where the Secretary has probable cause to believe that the misbranding is in a material respect false, misleading, or fraudulent. This will permit protection of the public against such nostrums as a brew of weeds labeled as a treatment for diabetes and against innumerable other, cheats and frauds which at best rob the consumer's pocketbook, and at worst rob him of health or life through his mistaken reliance upon them while his disease progresses unchecked. With this change the seizure section will continue to function as a means of arresting the bullet in flight before it claims its victim, although the administrative agency will have materially

these provisions were very carefully considered, and that Congress eliminated a provision which would have allowed the courts to restrain multiple seizures.

That the district court lacked jurisdiction to substitute itself for the Administrator by trying de novo the issue of misleading labeling or to review the Administrator's preliminary determination of probale cause appears not only from the general statutory plan, which vests in the libel courts sole authority to hear the merits of the cases, but from other factors as well. Several sections of the Federal Food, Drug and Cosmetic Act authorize judicial review of administrative action. Sections 505(h), 701(f), 21 U. S. C. 355(h) and 371(f). The absence of any such provision with respect to the preliminary finding of probable cause manifests a legislative intent that there be no review of such a finding, much more clearly than in the statute before the Court in Switchmen's... Union v. National Mediation Board, 320 U. S. 297. Furthermore, the finding as to probable cause is obviously preliminary in nature. All it does is to permit the institution of law suits, in which the controversial issues may be submitted to a court. Preliminary orders are not reviewable in an injunction suit when they culminate in further administrative action. Rochester Telephone Corp. v. United States, 307 U. S. 125, 130-131, and cases cited. When the preliminary administrative de-

less latitude, in making multiple seizures, when it had under the present law for the past 30 years."

The committee eliminated the provision of the Senate bill which gave the district courts jurisdiction to restrain a multiplicity of seizure actions. *Dunn*, pp. 429, 558. And finally the conference committee inserted the words "without hearing" in the provision requiring the Administrator to make a finding as to probable cause. *Dunn*, pp. 974, 992-3.

termination merely has the effect of authorizing the filing of lawsuits, the absence of jurisdiction in any other tribunal to review the administrative finding should be even clearer.

Under Section 304, the administrative finding of, probable cause is to be made without hearing, undoubtedly because a hearing would follow immediately in the libel proceeding. But the court below held a hearing de novo on the "merits" of the case in order to determine whether the Administrator should have made the preliminary finding. Cf. Shields v. Utah Idaho R. Co., 305 U. S. 177, 185; and Monongahela Bridge Co. v. United States, 216 U. S. 177. We submit that this plainly was not within the authority of the district court.

The procedure followed by the district court is not only clearly contrary to the congressional policy embodied in the statute, but is contrary to the public interest which that policy was designed toprotect—the safeguarding of the public health and purse against deception. The sanction of multiple actions is essential to arrest the distribution of a dangerous product, à fraudulent product, or a materially misleading product before it has claimed its victims and before irreparable injury is done. Without the sanction, there is no way in which dangerous, fraudulent, or seriously misleading drugs may be removed from the market and held within the custody of law pending a determination of the alleged misbranding. Under the decision of the three-judge court, all persons who distribute seriously misleading drugs throughout the country would have the right to challenge the Government's libel allegations in injunction suits in the District of Columbia whenever the Government thought it

in the public interest to seize more than one shipment of the product. This might well stay the arm of enforcement for months while either the misleading character of the labeling or the "probable cause", issue was in litigation. It was precisely to avoid the evils of such delay that the Administrator was authorized to make the determination of probable cause without hearing. If the court has the right to try the merits of the issue de novo, the beneficial effects of the expeditious procedure prescribed for administrative action are nullified; and great public harm can be done through widespread distribution of seriously mislabeled articles before the administrative officials may report the shipments of contraband for the institution of appropriate action.

More is involved here than the rights of the parties litigant. The public has an important stake in the outcome. No means exist to protect the consumer from the consequences of protracted proceedings. The injury to the public is direct in terms of money expended for a materially misbranded drug and in terms of health hazards inherent in experimenting with the drug in the treatment of what may well be serious disorders which require prompt, competent medical attention. This was deemed by Congress to outweigh possible harm to purveyors of drugs through temporary interruption of their business.

C. Other Errors of the Court Below

The defendants have challenged many other rulings of the district court, each of which would be ground for reversal. These relate to (1) the probing of the mental processes of administrative

officials; (2) the scope of the injunction that issued; (3) the findings of arbitrary and capricious action in the administrative process; (4) the finding that the labeling was not misleading; (5) the evidence and findings as to plaintiff's good faith; (6) unreasonable curtailment of defendants' right to cross-examination; (7) the improper admission of evidence in support of the plaintiff's case; and (8) the exclusion of proper evidence offered to support the defendants' case.

Many of these errors are serious and important. Inasmuch, however, as the two major questions already treated are sufficient to dispose of the case, and are clearly substantial, it does not seem necessary to discuss these additional points in this statement. Since this case is one required to be heard by a district court of three judges, the Supreme Court has jurisdiction of the case on appeal, and that jurisdiction extends to every question involved in the case. Sterling v. Constantin, 287 U. S. 378, 393, 394; Siler v. Louisville & Nashville R.R. Co., 213 U. S. 175; and Horner v. United States, 143 U. S. 570, 576.

CONCLUSION

The question as to the lack of jurisdiction in the court below to determine whether plaintiff's labeling was misleading and to review the administrator's preliminary determination of probable cause was argued before this court on the application for prohibition and mandamus last May. We believe that plaintiff's contentions with respect to that point, as well as on the question of constitutionality, though accepted below, are plainly without merit. We respectfully suggest that this Court may find this case an appropriate one for reversal

without further argument, and dismissal of the complaint. Securities and Exchange Commission v. Otis d' Co., No. 244, this Term, decided October 17, 1949.

Respectfully submitted,

PHILIP B. PERLMAN, Solicitor General.

JANUARY, 1950

APPENDIX

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Civil Action No. 5208-48

MYTINGER & CASSELBERRY, INC., PLAINTIFF

v.

OSCAR R. EWING, ADMINISTRATOR, ET AL., DEFEND-

PERMANENT INJUNCTION

This cause came on to be tried upon the issues raised in plaintiff's complaint for a permanent injunction as set forth in the Pre-Trial Order herein. After hearing and considering the evidence presented at the trial and upon the Findings of Fact and Conclusions of Law made and filed herein, it is by this Special Three-Judge Statutory United States District Court for the District of Columbia this 14th day of December, 1949,

Adjudged, ordered and decreed that the defendants, and each of them, their successors in office, their agents, servants, employees, attorneys and all persons in active concert and participation with them be and hereby are permanently enjoined from continuing or causing to be continued the prosecution of any of the libel for condemnation actions now pending against Nutrilite Food Supplement;

and it is further

Adjudged, ordered and decreted that the defendants, and each of them, their successors in office, their agents, servants, employees, attorneys, and all persons in active concert and participation with them be and hereby are permanently enjoined from instituting or causing to be instituted any further or additional libel for condemnation actions, or any other actions, against Nutrilite Food Supple-

ment under that part of 21 U.S.C. 334(a) herein held to be unconstitutional to wit: "such limitations shall not apply . . . when the Administrator has probable cause to believe from the facts found, without hearing, by him or any officer or employee of the agency that . . . the labeling of the misbranded article . . . would be in a material respect misleading to the injury or damage of the purchaser or consumer.

Bennett C. Clark,

Circuit Judge.

T. Alan Goldsborough,

District Judge.

Edward A. Tamm,

District Judge.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

. Civil Action No. 5208-48

MYTINGER & CASSELBERRY, INC., PLAINTIFF

118.

OSCAR R. EWING, ADMINISTRATOR, ET AL., DEFEND-

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This cause came on to be heard before this specially constituted Court of three judges convened persuant to the provisions of Section 2284, Title 28, U.S.C. Evidence and briefs having been submitted, oral argument of counsel had and the Court being now duly advised in the premises makes the following Findings of Fact and enters the following Conclusions of Law:

FINDINGS OF FACT

1. Plaintiff is a California corporation, having its principal place of business in the City of Long.

Beach, California. Defendant Oscar R. Ewing is the Administrator of the Federal Security Agency; Defendants Paul B. Dunbar, Charles W. Crawford, Louis D. Elliott and George P. Parrick are the Commissioner, Associate Commissioner and Assistant Commissioners, respectively, of the Food and Drug Administration of the Federal Security Agency; and Defendant J. Howard McGrath is the Attorney General of the United States and was substituted as a defendant in place of Tom C. Clark on October 17, 1949. Defendants are all charged by law with the administration and enforcement of the Federal Food, Drug and Cosmetic Act of 1938.

- 2. This suit arises from administrative action taken by the defendants under that part of Section 304(a) of the Federal Food, Drug and Cosmetic Act (21 U. S. C. 301, 334(a)) which provides that more than one libel for condemnation proceeding may be brought upon the same alleged misbranding "when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employe of the Agency that . . . the labeling of the misbranded article . . . would be in a material respect misleading to the injury or damage of the purchaser or consumer"; and under Sections 2282 and 2284 of Title 28 of the United States Code, Judiciary. and Judicial Procedure, which provides the procedure by which this court was convened to hear an application to restrain the enforcement, operation, or execution of the Federal Food, Drug and Cosmetic Act (21 U.S. C. 301 et seq.) for repugnance to the United States Constitution. (Complaint, Par. 2; Answer, Third Defense, Par. 2.)
 - 3. The plaintiff is the exclusive national distributor of a food supplement consisting of multiple vitamins and minerals sold under the trade name of "Nutrilite Food Supplement" (hereinafter called Nutrilite) through more than 5,000 distributors throughout the United States.

- 4. Nutrilite contains certain vitamins and minerals in a balanced proportion and in amounts claimed by some experts in the field as essential in human nutrition, plus extracts from alfalfa, parsley and watercress.
- or combination of substance or material or combination of substances or materials harmful or deleterious in any manner to human users thereof when taken in suggested dosage. No claim has been made by any Federal, State or other governmental agency that Nutrilite is adulterated or harmful in any manner to the health of human users thereof, insofar as the record before the court shows.
- 6. The label of the package in which Nutrilite was and is sold complies with all requirements of the Food, Drug and Cosmetic Act of 1938.
- 7. The objection of the defendants to the sale of Nutrilite, which is the basis of this action, is the use by plaintiff of an advertising pamphlet entitled "How to Get Well and Stay Well". Nutrilite is sold directly to users thereof and this pamphlet is used in making about 40% of the initial sales of Nutrilite.
- 8. The product now sold as Nutrilite was first marketed about 1933; defendants' records show they received information about it in 1939 and had correspondence about it in 1940; plaintiff has been its exclusive national distributor since 1945; defendants received their first copies of the then current edition of the pamphlet "How to Get Well and Stay Well" on December 5, 1946, together with names and addresses of certain of plaintiff's distributors outside of California.
- 9. In June 1947, the Food and Drug Administration sent plaintiff a notice of a hearing under Section 305 of the Food, Drug and Cosmetic Act of 1938. This notice and hearing are provided for prior to institution of criminal proceedings under the Act and said notice provided that it related

solely to "possible criminal action" and not to action "involving the seizure of the article" in libel cases. At the time of the hearing, July 15, 1947, Nutrilite Products had been in business some 15 years and up to 5 years before the time of said hearing Nutrilite representatives and been bringing Nutrilite labeling to the Los Angeles office of ... the Food and Drug Administration for comment and there had been no change in the labeling in the preceding five years. Neither the notice nor the statements of the Food and Drug Administration representative at the hearing specified any exact objections to particular language in the then current edition of the pamphlet "How to Get Well and Stay Well", but plaintiff's attorney advised plaintiff he thought he understood the objections of the Food and Drug Administration and he advised the Food and Drug Administration's representative that the pamphlet would be revised to eliminate these objections.

- and Drug Administration on October 4, 1947, that the rewriting of plaintiff's pamphlet had commenced promptly and was progressing as rapidly as possible considering the quantity of the material involved and the corrections required by him and that when finally completed he was sure none of the literature of plaintiff would be objectionable to said Administration.
- 11. There are three editions of the plaintiff's advertising pamphlet, "How to Get Well and Stay Well", which are involved in the libel seizure cases, hereinafter described: the 58-page edition which was used by plaintiff from January 1948 until a few days after the first seizure in October, 1948, and which is identified in the record as plaintiff's Exhibit #1; the 36-page edition consisting of the first 36 pages of the 58-page edition, which was used from the time the 58-page edition was discontinued up to about December 1, 1948, and which is identified in the record as plaintiff's Exhibit #2;

and the 42-page edition consisting of the 36-page edition changed slightly in non-substantial statements plus 6 additional pages, which has been used from about December 1, 1948 up to the time of the trial herein, and which is identified in the record as plaintiff's Exhibit #3.

- 12. (a) Three editions of the advertising pamphlet "How to Get Well and Stav Well" which are involved in and form the basis of the seizure actions hereinafter described, were written and pared chiefly by William S. Casselberry, President of the plaintiff corporation. He has an A.B. degree from the University of California and M.A. and Ph.D degrees from Stanford University. Prior to writing "How to Get Well and Stay Well" the read some medical and nutritional literature on the subject of vitamins and minerals. In the preparation of the three pamphlets he relied upon some scientific and medical treatises; surveys made by the medical profession with respect to the use of. vitamins and minerals; publications of the Federal Government relating to the amount of vitamins. and minerals required in the diet of humans and the efficacy of vitamins and minerals in human nutrition; and the findings and statements made by the Food and Drug Administration with respect to the need for and desirability of vitamins and minerals in the human diet.
- (b) The rewriting of the pamphlet required a period of approximately five months. During this period Dr. Casselberry checked the various drafts of the pamphlet with his company's attorney, the chemist who discovered and developed Nutrilite's secret base, and with neighbors to get the reactions of laymen to the pamphlet.
- (c) Plaintiff's attorney, who supervised the rewriting, has specialized in the Food and Drug Act field for many years. He has in his library, and has read, a number of books and scientific writings written by medical doctors and others in the field of nutrition, vitamins and minerals. Defendants

have stated that he is an experienced attorney in this field. He has approved the final drafts of each edition of the pamphlet before plaintiff began using them.

- (d) The beneficial effects of vitamins and minerals for nutritional deficiencies is a well established medical fact. Many of the statements in the pamphlet about the beneficial effects of particular vitamins and minerals for nutritional deficiencies are confirmed by the admissions of the defendants herein.
- (e) The three pamphlets (P.'s Exs. #1, 2 and 3), when read as a whole and fairly interpreted, without lifting statements therein out of context, do no more than represent that Nutrilite is a vitaminmineral food supplement designed and intended to build up the bodies of human users thereof in order that it may aid nature to help the users enjoy better health through better nutrition. Said pamphlets do not represent to the minds of ordinary, reasonable and prudent persons that all of the symptoms, conditions and diseases of the human body necessarily or generally result from dietary deficiencies alone, or that all of the symptoms, conditions and diseases of the human body can be prevented, cured or treated by the use of Nutrilite, and said pamphlets do not represent, suggest, or imply that Nutrilite is a medicine or drug, or that it is efficacious or beneficial in the prevention, treatment or cure of all diseases.

These pamphlets represent the product only as a food supplement containing vitamins and minerals beneficial to building up health and bodies and in a 'eviating, in some but not in all instances, symptous resulting from vitamin and mineral deficienciatin the diet. Purchasers and consumers do not uncerstand from these pamphlets that Nutrilite is a treatment or cure for any disease. The defendants' own survey to determine the impression gained by purchasers and consumers of the representations contained in these pamphlets under customary

conditions of purchase and use reveals that the users interviewed uniformly came to these conclusions and understandings of the statements in the pamphlets.

- (f) These three pamphlets when read as a whole are not fraudulent, misleading in a material respect to the injury or damage of the purchaser or consumer, or false or misleading in any particular. Neither Nutrilite nor its labeling has been made the basis of a prior judgment in favor of the United States in any case or proceedings finding it to be misbranded or adulterated, nor do these pamphlets misbrand the product Nutrilite Food Supplement within the intent of the provisions of the Food, Drug and Cosmetic Act of 1938. It is therefore found that the plaintiff has been and is acting in good faith in preparing and using these pamphlets.
- 13. After the plaintiff's rewriting of the pamphlet, and its publication in January, 1948, plaintiff learned that agents of the Food and Drug Administration were interrogating some of plaintiff's distributors and customers. In order to determine the basis for such interrogations, plaintiff arranged a meeting with representatives of the Food and Drug Administration at the Administration's office in Los Angeles. Plaintiff stated to the Chief-of said Administration's office that it wished to comply with every phase of the Food, Drug and Cosmetic Act and asked whether the investigation and interrogations were prompted by a belief that any part of plaintiff's label or labeling in any way violated any provision of said Act. The said Chief advised plaintiff that the investigation and interrogations were merely routine in nature and said Chief made no statement implying or suggesting that the Food and Drug Administration had any objection to the pamphlet "How to Get Well and Stay Well".

Plaintiff further stated to said Chief that should any question arise any time in the future concerning the alleged violation of said Act (misbranding) by any product distributed by plaintiff or in connection with any phase of plaintiff's business or operations, that if the Food and Drug Administration would notify the plaintiff thereof immediately when such question arose, plaintiff would do its utmost to comply with the views of the Food and Drug Administration.

- 14. On September 15, 1948, a secret indictment was returned in Los Angeles against the plaintiff's two principal stockholders, Lee S. Mytinger and William S. Casselberry, based upon allegations of misbranding of Nutrilite by the edition of the pamphlet "How to Get Well and Stay Well" obtained by defendants on December 5, 1946, products shipped by plaintiffs on January 3, 1947 and February 26, 1947, and which were involved in the notice and hearing thereon in July, 1947. The Federal Judge to whom this indictment was assigned for trial has advised the parties that he considers the trial a waste of Government money due to the discontinuance of the labeling there questioned. This indictment has not yet been set for trial.
- 15. On October 6, 1948, without prior notice to plaintiffs, the defendants instituted or caused to be instituted and commenced a libel action under which some packages of Nutrilite and some copies of the 58-page pamphlet "How to Get. Well and Stay Well" were seized in Belleville, New Jersey. Said libel alleged the misbranding of Nutrilite through the use of pages 37 through 58 of the 58-page edition of said pamphlet.
- 16. On September 28, 1948, defendant Crawford had authorized said seizure action of October 6, 1948, in Belleville, New Jersey, without reading pages 1 through 36 of this 58-page pamphlet. A reading of pages 1 through 36 of this pamphlet is hereby found to be essential in fairly interpreting pages 37 through 58.
- 17. On September 30, 1948 defendant Crawford authorized multiple seizures of Nutrilite in an exparte secret decision holding the 58-page pamphlet,

would be and is misleading in a material respect to the injury or damage of the purchaser or consumer. This decision was made without reading all of the 58-page pamphlet or re-reading pages 37-58, and it is admitted that defendant Crawford had not read all of the 58-page pamphlet prior to January 28, 1949. When this decision was made he had before him no facts showing injury or damage by Nutrilite or the 58-page pamphlet to any purchaser or consumer of Nutrilite and no facts showing that any user, purchaser or consumer of Nutrilite had made any complaint against the product or the 58-page pamphlet. No notice or copy of this decision was given or disclosed to plaintiff-and plaintiff's first knowledge of its existence and contents came on January 17, 1949, when defendants filed a copy thereof in this Court.

Defendant Crawford is not a nutritional expert but claimed he had before him this time (but not on September 28), and relied upon, a so-called finding of fact in writing which purported to be signed by a Dr. Robert C. Butz, an employe of the Food and Drug Administration, and which was dated September 30, 1948. Dr. Butz was not an employe of the Food and Drug Administration at the time of

the trial of this cause.

18. (a) Defendants' actions in initiating and carrying out the multiple seizures of Nutrilite are primarily attributed by them to certain findings of fact on plaintiff's pamphlets entitled "How to Get Well and Stay Well" purportedly by Dr. Robert C. Butz, then an employe of the Food and Drug Administration. The defendants who had made said decisions each testified that they had not discussed said findings with Dr. Butz. These findings were offered in evidence by defendants and received for the limited purpose of proving their existence as a part of the decision made by defendant Crawford and the decisions referred to herein as having been made by defendants Larrick, Dunbar and Mr. Kingsley, in holding said pamphlets to be misleading, and not as proof of the facts contained in said

- findings. Dr. Butz was not produced as a witness and no evidence was offered that he actually and personally made the findings or that he based them upon plaintiff's product or pamphlets.
- (b) The defendants admitted in open Court that they had not contacted Dr. Butz to see if he was available to them as a witness, offered no proof of his unavailability as a witness, and in fact stated defendants would not make any effort to obtain him as a witness. After specifically warning Counsel for defendants that these circumstances would cause the Court to draw an unfavorable inference against defendants on the qualifications of Dr. Butz, and defendants' right to rely upon him, the Court admitted into evidence a deposition given by Dr. Butz as an adverse witness, under subpoena, of the plaintiff.
- (c) In the deposition he repudiated some of the statements in said findings. The deposition indicated he consulted four medical doctors of the Food and Drug Administration on vitamins and minerals in general, but not on Nutrilite in particular. He had seen no assay or analysis of the contents of Nutrilite. He did not read the 58-page pamphlet in connection with the finding of September 30, 1948, but relied upon excerpts therefrom. He did not connect or identify the statements in his findings with any representations in the 58, 36 or 42-page pamphlet.
- (d) The four medical doctors employed by the Food and Drug Administration whom Dr. Butz named as his consultants did not testify herein. Defendants have never conducted any experiments to determine the effect of Nutrilite upon deficiency diseases or any other ailment.
- (e) From the facts herein, the Court finds that the defendants Crawford, Larrick, Dunbar and Mr. Kingsley, when they made their respective decisions described herein acted arbitrarily, capriciously and unreasonably in placing reliance upon

any of the so-called findings of Dr. Butz, the circumstances under which the findings were prepared, the contents thereof, the knowledge of those making decisions on plaintiff's said pamphlets, their actual reliance upon Dr. Butz, and the other actions of defendants herein which are claimed to be connected with the purported findings of Dr. Butz. It is further found that defendants' failure to produce or to try to produce Dr. Butz as a witness raises an inference that if he had testified in person his testimony would have been adverse to defendants.

19. On October 11, 1948, plaintiff received a copy of the libel papers filed in the Belleville, New Jersey, case on October 6, 1948, and learned therefrom for the first time that defendants were objecting to pages 37 through 58 of the 58-page pamphlet. Plaintiff immediately, on the same day, sent telegrams to all of its top agents throughout the United States instructing them in part as follows:

"Inform all agents and distributors in your group immediately that pending court ruling pages 37 through 58 inclusive of customer book . . . must not be used in selling Nutrilite. Remove pages 37 to 58 by cutting along fold with sharp knife. Wrap, seal and place disputed material in third party's hands to be held pending final ruling. Books in hands of prospects, junior distributors and customers to be treated in same way. Full explanation will appear with Nutrilite News, but follow above instructions at once."

A bulletin containing a full explanation was then mailed directly to all of plaintiff's agents and distributors to insure that every salesman in plaintiff's organization would get the information on discontinuance of use of pages 37-58 and would follow instructions. This explanation stated that regardless of whether the Food and Drug Administration

is right or wrong, the plaintiff wanted to follow that Administration's views.

20. On October 12, 1948, the plaintiff's attorney advised the Food and Drug Administration in Washington, D. C., by letter, that use of pages 37 through 58 of the 58-page pamphlet had been ordered to be discontinued by all of plaintiff's agents and distributors by said telegram and said bulletin immediately upon receipt of said libel papers. The also advised:

"In this connection I want to say that the filing of this libel in New Jersey was the first. intimation that we had received that any of the literature we are using at present was objectionable to your office. In the future I will appreciate it if you will advise me if you find anything in our literature that you take exceptions to: Mytinger and Casselberry are a reputable firm, and are desirous of co-operating with your Agency in every way possible. I need not point out that the offense of 'misbranding' is not a well defined one in the light of present. day scientific knowledge, and it is very easy for a firm in the nutritional supplement field to make statements in the best of faith which do not 'square' with the views of your office. this case a letter from your Agency pointing out your objections would bring a correction without the necessity of court action.

"With mutual cooperation, I believe that much trouble and expense can be saved for all partice concerned."

This letter and the facts set forth in paragraph 19 hereof show plaintiff was, in good faith, trying to comply with defendants' interpretations of the Food, Drug and Cosmetic Act of 1938.

21. On October 19, 1948, after failing to answer this said letter of October 12, 1948, the defendants made a second similar seizure in New York City.

- 22. The libel papers in this said second seizure action and the libel papers in the eight additional seizure actions described hereinafter contain statements which are in substance identical. There are no separate issues of fact or law necessitating more than one such action, as a decision in the first libel action would settle all said issues with respect to the alleged misbranding of Nutrilite by the use of the three editions of the pamphlet "How to Get Well and Stay Well." These libel seizure actions having been instituted in widely separated jurisdictions in the United States inflicted unnecessary punishment and expense on the plaintiff.
- 23. The October 19, 1948 seizure and the ten other seizures hereinafter found to have been made and instituted against plaintiff's, product Nutrilite, were made under the provisions of Section 334(a) of Title 21 of the United States Code which permits multiple libel seizure actions based upon the same alleged misbranding "when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employe of the agency . . . that the labeling of the misbranded article . . . would be in a material respect misleading to the injury or damage of the purchaser or consumer."
- 24. On approximately October 18, 1948, plaintiff agreed to the request of the Government that the indictment matter in California be continued to December 5, 1948, upon plaintiff's understanding that the defendants contemplated making no more seizures. However, other seizures were made thereafter.
- 25. On October 28, 1948, the third said similar seizure was made in Buffalo, New York.
- 26. In November, 1948, plaintiff requested defendants to agree to consolidation and trial in the United States District Court in Los Angeles, within 25 miles of plaintiff's principal place of business in Long Beach, of the said three libel seizures which

had then been filed. Defendants refused said request and informed plaintiff that they would agree to consolidation for trial of the three cases in Phoenix, Arizona, or in San Francisco, California, only. Defendants at the same time advised the plaintiff that they had already approved further seizures and did not promise to withhold said seizures if the first three were consolidated for trial.

- 27. After plaintiff and its agents and distributors had removed the pages objected to in the first libel action, the remaining 36 pages of the 58-page edition of "How to Get Well and Stay Well" were used for a short period while an epilogue was being written to complete said booklet. This 36-page edition is identical with the first 36 pages of the 58-page edition of said pamphlet which Defendant Crawford had before him in making his decision of September 30, 1948. Subsequently, 6 pages were added to the said 36-page booklet which did not alter or enlarge the sense and meaning of the first 36 pages. The addition of these pages resulted in the. so-called 42-page edition of "How to Get Well and Stay Well" which has been used by plaintiff since approximately December 1, 1948.
- 28. On December 1, 1948, the fourth said similar seizure was made in Hastings, Nebraska.
- 29. On December 2, 1948, the defendant Larrick made an ex parte decision holding that the 36-page edition of the pamphlet "How to Get Well and Stay Well" would be and is misleading in a material respect to the injury or damage of the purchaser or consumer. Defendant Larrick at the time of his December 2, 1948 decision, knew that defendant Crawford, in his decision of September 30, 1948, had these 36 pages before him and that defendant Crawford had not found these 36 pages to be objectionable and that said 36 pages of the said 58-page pamphlet were identical with the 36-page pamphlet before him. He knew of the communication from plaintiff's attorney requesting

an apportunity to comply with future objections, as described in paragraph 13 hereof. He had no facts before him at the time of his decision showing that Nutrilite or any of its labeling, including the 36-page pamphlet, had damaged or injured any purchaser or consumer. He is not a mutritional expert and claimed that he relied on a socalled finding of fact purportedly made by Dr. Robert C. Butz referred to in paragraph 18 hereof and "accepted Dr. Butz' conclusions as to the misleading character of the statements in it". Said decision of defendant Larrick was not disclosed to plaintiff until Jan. 17, 1949, when a copy thereof was filed in the instant case. The findings in said paragraph 18 as to Dr. Butz and defendant Larrick apply here.

30. On December 9, 1948, defendant Dunbar made an ex parte decision holding that the 42-page edition of plaintiff's pamphlet "How to Get Well and Stay Well' would be and is misleading in a material respect to the injury or damage of the purchaser or consumer. This matter was brought to him for decision by a Mr. Murray, an employe of the Food and Drug Administration and author of a memorandum indicating that the defendants planned to "keep the pressure" on plaintiff. Murray informed defendant Dunbar that he (Murray) was considering a number of seizure recommendations against Nutrilite based on the labeling contained in the 42-page pamphlet. Dunbar read only certain unidentified parts of the pamphlet pointed out to him by Mr. Murray before making his decision that the pamphlet was misleading and relied on oral statements made to him by Mr. Murray. He had before him at the time. of his decision no facts showing damage or injury to any purchaser or consumer by Nutrilite or any of plaintiff's labeling, and had not seen nor heard of any complaints that Nutrilite or its labeling had injured or damaged any person. He did not consider the report on the defendants' own survey to determine how purchasers and consumers

interpreted this pamphlet, although it was then in his files. He, too, testified that he was not a nutritional expert but claimed he relied upon a finding of fact purportedly made by Dr. Butz and the findings in paragraph 18 hereof on Dr. Butz and defendant Dunbar apply here. This decision of defendant Dunbar was not disclosed to plaintiff until January 17, 1949, when a copy thereof was filed in the instant case.

31. Through the actions of defendants, additional similar seizures of Nutrilite and said pamphlets were then made in the following places:

Belleville, New Jersey December 15, 1948 Spokane, Washington December 23, 1948 Seattle, Washington December 30, 1948 Clarkfield, Minnesota December 31, 1948 St. Petersburg, Florida January 4, 1949 Chicago, Illinois January 3 & 4, 1949

Finding 22 hereof covers the similarity of issues in these cases. These seizures were made after defendants had made a survey to determine whether plaintiff's said pamphlets were misleading in any particular to consumers and purchasers thereof under customary conditions of purchase and use and after said survey had revealed that said pamphlets were not in fact misleading in any particular to purchasers and consumers.

- 32. (a) On December 30, 1948, the instant injunction action was filed. At this time it was the intention and plan of the defendants to file many more libel seizure actions and seize Nutrilite throughout the Nation. The Food and Drug inspectors knew of this general policy.
- (b) It was the plan of defendants to keep a sustained pressure against plaintiff through such seizures until an injunction was granted in the instant action or the indictment case in California based upon the discontinued literature went to trial. This plan of defendants is set forth in writing in a memorandum written by A. G. Murray, an

administrative officer of the Food and Drug Administration, and addressed to the Division of Field Operations of the Food and Drug Administration. It was not denied that Mr. Murray was and is under the control of the defendants and that he was present in Court. No effort was made by the defendants to call Mr. Murray and explain the circumstances under which the memorandum was written and used. Defendant Larrick admitted that said memorandum was an accurate statement of defendants' policy in regard to plaintiff, and that said memorandum was circularized in the offices of the Food and Drug Administration and 'created a general impression in said offices highly prejudicial to plaintiff. The Court presumes, from defendants' refusal to call Mr. Murray as a witness, that his testimony, not only in regard to the contents and use of said memorandum, but also in regard to the seizure recommendations presented to defendant Dunbar by him, would have been adverse to the defendants.

- (e) Defendants made no effort to secure an early trial in the libel cases and in order to effect seizures more quickly, mimeographed copies of the booklets "How to Get Well and Stay Well" were prepared for transmission to United States Attorneys.
- 33. On January 17, 1949, defendants filed in the United States District Court for the District of Columbia a motion to dismiss the complaint herein.
- 34. On January 24, 1949, Judge David A. Pine of the United States District Court for the District of Columbia found that the actions of the defendants in rendering said decisions were "unfair", "drastic", "shocking", and "harsh" and held that the decisions of defendants Crawford, Larrick and Dunbar, described supra, were unlawful because the Administrator of the Federal Security Agency did not have the authority to delegate this power to make such decisions to said defendants.
- 35. (a) On January 28, 1949, at the request of defendant Dunbar, the Acting Administrator of

the Federal Security Agency, J. Donald Kingsley, made three decisions identical in language with the three decisions of defendants Crawford, Larrick and Dunbar, supra, (paragraphs 17, 29 and 30) respectively. He is not a nutritional expert but claimed he relied upon three so-called findings purportedly made by Dr. Robert C. Butz.

- (b) Kingsley did not talk to Dr. Butz or identify the Butz findings contained in defendants' Ex. No. 23 as those upon which he (Kingsley) relied in connection with any particular one of his three decisions. He is uncertain as to which version or versions of the pamphlet he had before him, and did not read all three pamphlets before making his decision condemning all three as misleading in a material respect to the injury or damage of the purchaser or consumer. Kingsley did not consider the defendants' own investigation and report thereon in his files showing that consumers and purchasers did not receive a misleading impression from reading plaintiff's pamphlets.
- (c) Kingsley had no facts before him showing injury or damage to any purchaser or consumer of Nutrilite by the product or its labeling, and had no facts before him showing any complaints of injury or damage from Nutrilite or its labeling.
- (d) Kingsley, as Acting Administrator of the Federal Security Agency, twice refused requests of plaintiff that he grant it a hearing prior to making a decision on whether Nutrilite was misbranded by said labeling, the three editions of the pamphlet "How to Get Well and Stay Well". Said requests advised him that if officials of the Food and Drug Administration asked him to make a decision that plaintiff's advertising and labeling were misleading in a material respect to the injury or damage of the purchasers or consumers of Nutrilite, plaintiff could present him with the full and true facts showing that the labeling of Nutrilite was not misleading in any respect. He was advised by plaintiff that the consequences of an erroneous decision on

this matter by him would be that plaintiff would be put out of business completely and irreparably damaged by the multiple seizures so authorized and threatened by defendants prior to any possible opportunity plaintiff might have to defend itself against said decision. He twice denied this request for a hearing prior to his decisions, talked only to his own counsel and to defendants Dunbar and Crawford about the decision of Judge Pine, and made an ex parte decision that plaintiff's labeling is misleading. The findings in paragraph 18 hereof on Dr. Butz and Mr. Kingsley apply here.

- (e) Defendants did not produce Kingsley as a witness or prove that he was unavailable to them as a witness, and his deposition is incomplete. Counsel states therein that the deposition is to be completed at a later date when certain records, which defendants refused to produce at the time of the taking of the deposition, were made available under Court order. The order was made but the deposition was not completed. Defendants' failure to produce Kingsley as a witness, or to prove his unavailability to them as a witness, warrants an inference that if he had testified his testimony would have been adverse to defendants.
- 36. On March 3, 1948, Judge David A. Pine granted a motion to dismiss plaintiff's complaint with leave to amend and the Amended Complaint, which is before this Special Three-Judge Court, was then filed. A temporary restraining order was then signed enjoining defendants from making any further seizures of Nutrilite pendente lite.
- 37. On April 5, 1949, plaintiff filed a motion in the Federal District Court in Newark, New Jersey, to consolidate the ten libel actions for trial in Los Angeles, California, which motion defendants opposed. Said motion was argued, on Monday, September 19, 1949, at which time it was the defendants' general position that the defendants did not want the libel issues tried in Federal Court in Los Angeles. Three days later, on Thursday, September 22, 1949, however, the defendants filed an in-

junction action in the very Federal Court in Los-Angeles involving identical issues insofar as plaintiff's pamphlet "How to Get Well and Stay Well" is concerned. The defendants' action herein was deliberate and arbitrary to increase the plaintiff's irreparable damage. Defendants knew that plaintiff could consolidate all such actions and that the only accomplishment of the filing of the numerous seizure actions would be the irreparable injuries set forth in finding 39 herein.

38. The defendants have caused embargoes to be instituted and placed on Nutrilite prior to the institution of libel for condemnation proceedings in New York, New Jersey, Washington State, Florida, and various localities in the United States by requests to State and local health authorities, which embargoes naturally frightened agents, distributors and customers of Nutrilite and had very much the same damaging and injurious effect as the seizures. These embargoes obtained in widely scattered jurisdictions of the United States caused maximum and irreparable injury to plaintiff.

39. The seizure actions caused plaintiff a sales

loss of some \$100,000 per month from the time of the first seizure until the instant action was filed. and the defendants were restrained from making further seizures. The seizures had the effect of frightening plaintiff's agents and distributors, so that they worked less, and some resigned, with the net result of loss of morale among agents and distributors, loss in sales volume and loss of personnel. Unfavorable opinions and injurious information with respect to the labeling of plaintiff's product reached many private individuals and organizations. Publicity about the seizure cases initiated by defendants appeared in newspapers and magazines in a way which did injuriously damage plaintiff and this led to loss of customers. Plaintiff was compelled to hire counsel in the ten libel cases and put up bonds and costs in each case. The value of the Nutrilite seized by defendants in the ten libel

actions is \$6.822.17 and the product so seized willbe unsaleable if returned to plaintiff. The nature of plaintiff's business makes good-will of the public one of its most valuable assets and the acts of the defendants in the embargoes and seizure actions in widely separated parts of the United States has caused the plaintiffs in jury and damage. Defendants admit injury to plaintiff and that there has been a serious impact on plaintiff's rights by their actions, and that there is no provision of law requiring or permitting defendants to reimburse plaintiff for the damages berein found or for the injury or for destruction of its business and goodwill by the actions of the defendants, in the event of a determination of said libel actions in favor of The injury and damage to plaintiff which has occurred and which is threatened by defendants is therefore substantial and irreparable.

- 40. The defendants have never advised plaintiff of the particulars of plaintiff's literature considered to be objectionable by defendants. The defendants have not provided an opportunity to plaintiff whereby such literature could be corrected, revised and amended in a manner which would conform to the views of and be acceptable to the defendants.
- 41. That plaintiff would have been subjected to many additional seizures of its product throughout the United States in addition to the existing 11 seizures of its product, if not enjoined from so doing, is admitted by defendants. It was a general policy and plan of the defendants to make with all possible speed many seizures of plaintiff's product. Such additional seizures, and the product could be seized by defendants in the hands of more than 5,000 of plaintiff's distributors, would have the effect of destroying plaintiff's business prior to any possible adjudication of the disputed issues on plaintiff's labeling in any of the libel actions already filed or threatened.

- 42. There was and is no emergency involving injury or damage of any kind to the public or to any purchaser, consumer or user of Nutrilite or in connection with Nutrilite and plaintiff's use of the three pamphlets which constitute defendants' sole objection to Nutrilite's sale. Defendants have not, at any time, indicated or contended that there is an emergency or situation of compelling public necessity with respect to the labeling of plaintiff's product and no such emergency or situation did, in fact, exist at or prior to any of the actions of defendants described herein.
- 43. The evidence herein on the actions, conduct and course of action of defendants before and after the decisions of Crawford, Larrick, Dunbar and Kingsley described above reveal, as do their decisions and actions in making said decisions, that the defendants in making said decisions acted capriciously, arbitrarily, unreasonably, oppressively and unlawfully.

CONCLUSIONS OF LAW

The Court, upon the basis of the Findings of Fact herein, makes Conclusions of Law as follows:

- 1. This Court has jurisdiction to hear and determine this case.
- 2. The following provisions of the Food, Drug and Cosmetic Act of 1938, Section 334, Title 21, United States Code, are unconstitutional under the due process clause of the Fifth Amendment to the Constitution of the United States: "... such limitations shall not apply ... when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employe of the agency that ... the labeling of the misbranded article ... would be in a material respect misleading to the injury or damage of the purchaser or consumer." The defendants should be permanently enjoined from enforcing this unconstitutional provision against plaintiff.

7. The provisions just quoted in the second conclusion hereof were intended by the Congress to be and are hereby found to be separable from the remaining provisions of the said Act and said remaining provisions remain in full force and effect.

- 4. Defendants Crawford, Larrick, Dunbar, Kingsley and Ewing, in instituting multiple libel proceedings against the product Nutrilite Food Supplement without first affording the plaintiff a hearing on the issue of whether there was probable cause to believe that the labeling of the product was misleading in a material respect, acted arbitrarily, oppressively, and capriciously in violation of the Fifth Amendment to the Constitution.
- 5. The defendants and all persons acting in concert with them or under their direction, supervision, or control, should be permanently enjoined from instituting or maintaining any action or proceeding raising issues of fact or law that Nutrilite Food Supplement is misbranded under the Food, Drug and Cosmetic Act of 1938, by the plaintiff's pamphlets, Exhibits 1, 2 and 3, herein.

Bennett C. Clark,

Circuit Judge.

T. Alan Goldsborough,

District Judge.

Edward A. Tamm,

District Judge.

Dated: DECEMBER 1949.